



PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of

8

Complete if Known

Application Number	10/656,567
Filing Date	September 4, 2003
First Named Inventor	Daug, Edward D.
Art Unit	1014 1624
Examiner Name	To Be Assigned Z. TVCKER
Attorney Docket Number	016325-008510US

**U.S. PATENT DOCUMENTS+**

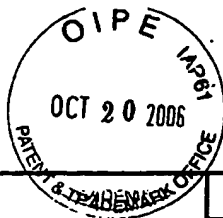
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
ET	1	3,378,582		04-16-1968	Bolhofer	
	2	3,444,299		05-13-1969	Wood et al.	
	3	3,469,009		09-23-1969	Klingbail	
	4	3,517,050		06-23-1970	Bolhofer	
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	14	4,146,623		03-1979	Parker	
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	39	6,013,659		01-11-2000	Goldfarb et al.	
ET	40	6,934,246		03-07-2000	Stevens et al.	

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**INFORMATION DISCLOSURE  
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Sheet 2

of

8

Complete if Known

Application Number 10/656,567

Filing Date September 4, 2003

First Named Inventor Dausg, Edward D.

Art Unit 4614 1624

Examiner Name To Be Assigned E. TUCKER

Attorney Docket Number 016325-008510US

**U.S. PATENT DOCUMENTS+**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
ZT	41	6,037,493	A	03-14-2000	Mathey et al.	
	42	6,069,272	A	05-30-2000	Crout et al.	
	43	6,093,830	A	07-25-2000	Yadav et al.	
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	46	6,201,000		03-13-2001	Luther et al.	
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	60	US 2005/0075396		04-07-2005	Luskey, et al.	

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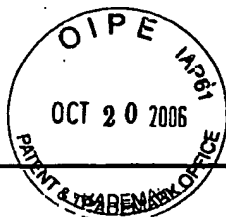
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
ZT	61	FR	1,476,525		04-1967	Merck & Co. Inc.		
	62	GB	1,182,008		02-1970	Roberts, Jr.		
	63	CA	967,978		05-1975	Merck & Co. Inc.	ABSTRACT	
	64	GB	1,403,309		08-20-1975	Merck & Co. Inc.		
	65	JP	53-15325	A2	02-13-1978	Fujisawa Pharmaceutical Co.		
	66	JP	53-71071	A	06-24-1978	Teijin Ltd.		
	67	EP	0 077 938	A2	05-04-1983	Mitsubishi Chemical Industries, Ltd.		
	68	EP	0 105 494	A2	04-18-1984	Hoechst A.G.		
	69	JP	60-109578	A	06-15-1986	Mitsubishi Chemical Industries, Ltd.		
	70	EP	0 306 708	A1	03-15-1989	Kanebo Ltd.		
	71	WO	92/17435		10-1992	Boehringer Mannheim GmbH		

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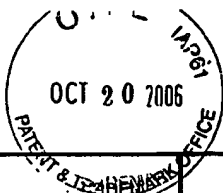
PTO/SB/08A (08-03)

Substitute for form 1449A/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10/656,567	
			Filing Date	September 4, 2003	
			First Named Inventor	Daug, Edward D.	
			Art Unit	4014-1624	
			Examiner Name	To Be Assigned E. TUCKER	
Sheet	3	of	8	Attorney Docket Number	016325-008510US

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
ET	72	WO	98/23252	A1	06-04-1998	Ciba Specialty Chemicals Holding Inc.		
ET	73	WO	99/11627	A1	03-31-1999	Ortho-McNeil Pharmaceutical, Inc.		
ET	74	WO	00/35886	A3	06-22-2000	Axys Pharmaceuticals, Inc.		
ET	75	WO	00/74666	A2	12-14-2000	Metabolex, Inc. et al.		
ET	76	EP	1 162 196	A1	12-12-2001	Japan Tobacco Inc.		
ET	77	WO	02/44113	A2	06-06-2002	Metabolex, Inc.		
ET	78	WO	04/112774	A1	12-29-2004	Metabolex, Inc.		
ET								

Examiner Signature		Date Considered	2 NOVEMBER 2006
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60127119 v1



PTO/SB/08B (08-03)

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet	4	of	8
<b>Complete if Known</b>			
Application Number		10/656,567	
Filing Date		September 4, 2003	
First Named Inventor		Daugis, Edward D.	
Art Unit		1814 1624	
Examiner Name		E. TUCKER	
Attorney Docket Number		016325-008510US	

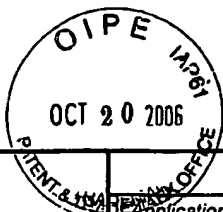
NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
2T	79	ARONOW, W.S. et al., "Effect of halofenate on serum uric acid," <i>Clin. Pharmacol. Ther.</i> , 1973, Vol. 14, pp 371-373.	
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Examiner Signature		Date Considered	8 NOVEMBER 2006
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**INFORMATION DISCLOSURE  
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(use as many sheets as necessary)

Sheet	5	of	8	Application Number	10/656,567
				Filing Date	September 4, 2003
				First Named Inventor	Daugis, Edward D.
				Art Unit	<del>4644</del> 1624
				Examiner Name	Z. TUCKER
				Attorney Docket Number	016325-008510US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
ZT	96	FANELLI, G.M., Jr., "Renal Excretion and Uricosuric Properties of Halofenate A Hypolipidemic Uricosuric Agent in the Chimpanzee," J. Pharmacol. Exp. Ther. 1972, Vol. 180, pp 377-396.	
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Examiner Signature		Date Considered	8 NOVEMBER 2006
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Sheet	6	of	8	Application Number	10/656,567
				Filing Date	September 4, 2003
				First Named Inventor	Daug, Edward D.
				Art Unit	4644 1624
				Examiner Name	E. TUCKER
				Attorney Docket Number	016325-008510US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
ZT	112	KELLER C. et al., "Die Benhandlung von Hyperlipidämie und Hyperurikämie mit 2-Acetamidoäthyl-(4-chlorophenyl)-(3-trifluoromethylphenoxy)-acetat (Halofenat), einem Derivat des Clofibrat," <i>Arzneimittelforschung</i> , 1976, Vol. 26, No. 12 pp 2221-2224.	
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Examiner  
SignatureDate  
Considered

8 NOVEMBER 2006

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

60127119 v1



PTO/SB/08B (08-03)

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet	7	of	8	Application Number	10/656,567
				Filing Date	September 4, 2003
				First Named Inventor	Daug, Edward D.
				Art Unit	1614 1624
				Examiner Name	Z. TVCKER
				Attorney Docket Number	016325-008510US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
ZT	129	METABOLEX, The Diabetes Biopharmaceutical Company, "Metabolic Diseases Drug Discovery & Development Summit," Strategic Research Institute, (May 6-7, 2002).	
	130	MINERS, J.O., et al., "Cytochrome P4502C9: an enzyme of major importance in human drug metabolism," J Clin Pharmacol, 1998, Vol. 45, pp 525-538.	
	131	MORGAN, J. P., et al., "Hypolipidemic, uricosuric, and thyroxine-displacing effects of MK-185 (halofenate)," Clin. Pharmacol. Therap., 1971, Vol. 12, No. 3, pp 517-524.	
	132	NEUMAN, J., et al., "A double-blind comparison of the hypolipidemic and hypouricemic action of halofenate and clofibrate in patients with hyperlipoproteinemia," The International Cardiovascular Society, pp 532-537.	
	133	PELKONEN, O., et al., "Inhibition and induction of human cytochrome P450 (CYP) enzymes," Xenobiotica, 1998, Vol. 28, No. 12, pp 1203-1253.	
	134	QU, et al., "Search for New Antiphytovirucides," Wujan Univ. Journal of National Science, 1998, Vol. 3 No. 2, pp 201-204.	
	135	QU, et al., "Some New Antiphytoviral Compounds Containing Trifluoromethyl Group," Wuhan Univ. Journal of National Science, 1996, Vol. 1, No. 2, pp 283-284.	
	136	RAVENSCROFT, P.J., et al., "Studies of the uricosuric action of the hypolipidemic drug halofenate," Clin. Pharmacol. Ther., 1973, Vol. 14, No. 4, pp 547-551.	
	137	REAVEN, G. M., "Insulin Resistance and Human Disease: A Short History," J. Basic & Clin. Phys. & Pharm., 1998, Vol. 9, No. 2-4, pp 387-406.	
	138	REAVEN, G. M., "Pathophysiology of Insulin Resistance in Human Disease," Physiol. Rev. 1995, Vol. 75, No. 3, pp 473-486.	
	139	RYAN, J. R., "The metabolic spectrum of halofenate," Int. J. Clin. Pharmacol., 1975, Vol. 12, No. 1/2, pp 239-243.	
	140	SAFAK, et al., "Synthesis of Some Benzimidazol Derivatives, and Their Effects on Serum Total Cholesterol and Triglyceride Levels in Rats," FABAD J. Farm. Sci., 1983, Vol. 8, No. 1, pp 19-29.	
	141	SCHAEFFER, S. "Trying to beat PPAR," BioCentury, The Bernstein Report on BioBusiness, (Reprint from June 14, 2004) pp 1-3.	
	142	SCHAPPEL, G.J., et al., "Efficacy and Interactions of Oxandrolone, Halofenate and Clofibrate in a Factorial Study on Experimental Acute Nephrotic Hyperlipidemia," The Journal of Pharmacology and Experimental Therapeutics, 1975, Vol. 194, No. 1, pp 274-284.	
	143	SCHLOSSTEIN, L.H., et al. "Studies with some novel uricosuric agents and their metabolites: correlation between clinical activity and drug-induced displacement of urate from its albumin-binding sites," J. Lab. Clin. Med., Vol. 82, No. 3, pp 412-418.	
Y	144	SIRTORI, C., et al., "Clinical Evaluation of MK-185: A New Hypolipidemic Drug," Lipids, 1971, 7, No. 2, pp 96-99.	
ZT	145	SKYLER, J.S., "Glucose Control in Type 2 Diabetes Mellitus," Annals of Internal Medicine, 1997, Vol. 127, No. 9, pp 837-838.	

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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
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		Filing Date	September 4, 2003
		First Named Inventor	Daug, Edward D.
		Art Unit	1644 1624
		Examiner Name	E. TUCKER
Sheet 8 of 8	Attorney Docket Number	016325-008510US	

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ET	146	STEINER, A., et al., "A Comparative Review of the Adverse Effects of Treatments for Hyperlipidaemia," Drug Safety, 1991, Vol. 6, No. 2, pp 118-130.	
ET	147	TASKINEN, M.R., "Lipid disorders in NIDDM: implications for treatment," Journal of Internal Medicine, 1998, Vol. 244, pp 361-370.	
ET	148	TRUST, R. I., et al., "(Aryloxy)[p-(aryloxy)phenyl]- and (Aryloxy)[p-arylthio)phenyl]acetic Acids and Esters as Hypolipidemic Agents," Journal of Medicinal Chemistry, 1979, Vol. 22, No. 9, pp 1068-1074.	
ET	149	TURNER, N., et al., "Insulin resistance, impaired glucose tolerance and non-insulin-dependent diabetes, pathologic mechanisms and treatment: Current status and therapeutic possibilities," Prog Drug Res., 1998, pp 33-94.	
ET	150	VARMA, et al., "Synthesis of Substituted 2-Phenylbenzothiazoles & 5(6)-Nitro-1, 3-disubstituted-benzimidazoline-2-thiones as CNS Active Agents," Indian Journal of Chemistry, 1988, Vol. 27B, No.5, pp 438-442.	
ET	151	VEDELL, E.S., et al., "Differential Effects of Chronic Halofenate Administration on Drug Metabolism in Man," Fed. Proc., 1972, Vol. 31, No. 2, pp 538.	
ET	152	WILSON, J., et al., (ed.) Disorders of Lipid Metabolism, Chapter 23, Textbook of Endocrinology, 9th Edition, 1998, W.B. Sanders Company, Philadelphia, PA. (all references cited therein)	
ET	153	WOLFRAM, G. et al., "Primarer Verteilungsraum und Plasmahalbwertszeit von intravenos verabreichtem Insulin," Verh. Dtsch. Ges. Inn. Med., 1973, Vol. 79, No. 1, pp 291-1293.	
ET	154	WRIGHT, A.D., et al., "UKPDS 28: A Randomized Trial of Efficacy of Early Addition of Metformin in Sulfonyleurea-Treated Type 2 Diabetes," Diabetes Care, 1998, Vol. 21, pp 87-92.	

Examiner Signature		Date Considered	8 NOVEMBER 2006
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